IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Andrew Szabo
Serial No.	:	09/400,649
Filed	:	September 21, 1999
For	:	NUTRITIONAL OPTIMIZATION SYSTEM AND METHOD
Examiner	:	Samuel Rimell
Group:		2175

Commissioner for Patents
P.O. Box 1450
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March 17, 2008

APPLICANTS REVISED REPLY BRIEF UNDER 37 C.F.R. §41.41(a)

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

SIR:

In response to the Communication from the Examiner refusing consideration of the Reply Brief filed May 8, 2007, and the Examiner's Answer dated March 9, 2007, the time for response to which expires May 9, 2007, Applicant herewith provides its Revised Reply Brief. Applicant has previously requested oral argument.

ARGUMENT

LEGAL STANDARD FOR ANTICIPATION

In Applicant's Brief, the standard for anticipation was imprecisely presented. Applicant therefore takes this opportunity to present the proper standard which should be applied by the Board. The Federal Circuit restated the applicable law in In Re Omeprazole Patent Litigation 04-1562, -1563, -1589 (Fed. Cir 2007), Sip. Op. at 11: "Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently. MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999). An anticipation analysis requires a comparison of the construed claim to the prior art. Helifix, Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000)."

Thus, the claims must be properly construed, and then the explicit or inherent teachings of the reference applied, to determine whether each and every claim limitation is disclosed.

CLAIM INTERPRETATION

Claim 29 provides the step of "(d) determining economic parameters associated with the subset of records." Claim 44 provides the step of "(c) determining a statistical risk relating to the set of records and the determined user relevance parameter." Claim 59 provides the step of "(b) determining a statistical risk associated with records within the class of information and the received specification."

It is further noted that claim 44, in contrast to claim 29, requires that the statistical risk related to both the set of records and the determined user relevance parameter. Even assuming *arguendo* that the Examiner's rejection of claim 29 on this point is valid, this additional language is neither taught nor suggested by Mayaud.

The Examiner asserts that "Drug allergies are a statistical risk associate[d] with a record of a drug in a database". However, the Examiner does not indicate how the mere user input of a "fact", i.e., the presence of absence of a drug allergy, corresponds with the method step of "determining a statistical risk associated with a respective record." Mayaud indeed does not apply any statistical methods or analyze any results based on probabilities. The Examiner indicates that because Applicant has not defined "statistical risk", nor provided a suitable definition, that he is free to interpret the language in any way necessary to support the rejection. Indeed, the term "statistical" has been previously defined. The meaning of "statistics" is well

understood by those of ordinary skill in the art, with the exercise of ordinary creativity, and there is no requirement for applicant to specifically define those terms and phrases which have an understood meaning in the art, and for which no modification of the existing understandings are intended. This meaning is contrasted with meaning of the word "hazard", which applicant respectfully submitted is quite distinct.

Since the determination of a "statistical risk" requires some reference to probabilities or likelihoods relating to an event having uncertain outcome, rather than certainties or presumptions of definiteness, it is clear that the "Drug Allergies" of Mayaud represent a distinct concept not encompassed by this claim language, and is perhaps better described by the word "hazard". Since the word "risk" has accepted meaning, which is clarified by the word "statistical", it is respectfully submitted that due deference to the scope of that meaning is required. Therefore, the Examiner is not free to formulate his own definition which is inconsistent with the specification, claims, and common usage. Therefore, applicants respectfully assert that the phrase has a known and accepted meaning in the art., consistent with applicant's assertions.

The Examiner alleges that the output of Mayaud, Fig. 11 "…will include a drug or drugs that have been automatically (by computer) optimized for both the risk to the patient and the economic cost. This is considered to be an automatic optimization since it is performed by the assistance of a computer program, and a joint optimization since it considers two separate variables (cost and allergic risk)." Assuming *arguendo* that the "statistical risk" determined by respective elements of claims 29, 44 and 59 is somehow disclosed by Mayaud, the prima facie case of anticipation must still fail.

A joint optimization of non-binary variables, such as "statistical risk" and "economic parameters" does not operate as a simple Boolean filter, which is apparently what is disclosed in Mayaud and represented in Fig. 11. Therefore, only by artificially constraining the "statistical risk" to a binary decision, and then using this decision to implement a simple filter, does the Examiner approach the present claim scope by analogy to Mayaud. In fact, there is simply no support for using statistical variables in the system described by Mayaud. The independent claims therefore require a determination of a description of some probability, rather than a presumed certainty, as is the case with the "Drug Allergies" of Mayaud.

Another approach is to consider whether Mayaud can indeed operate on the defined statistical risk parameter presented; that is, whether the optimization of the statistical risk and

economic parameters defined by the claims is taught by Mayaud. The Examiner trivializes the determined "statistical risk" to a medical certainty. However, the statistical risk is employed *after* determination, and in order to anticipate the claims, an input of the form defined by the claims should be usable. Thus, it is clear that the use of the phrase "statistical risk" in the claims, may, for example, represent a 50% probability. However, Mayaud teaches no capacity to receive, handle or process such an input, or to perform any optimization or analysis of this type of value. For example, if there is a 50% probability that the patient is allergic to Penicillin, how does the doctor input this representation, and what does the output look like? Since the plain meaning of the claim language is inconsistent with the Examiner's claim interpretation, that interpretation must be rejected.

The Examiner comments that applicant has not addressed the rejections specifically as formulated by him, and in particular failed to focus on the sections of the Mayaud reference cited. Mayaud, Col. 39, line 44-Col. 40, line 37 state:

> Further to enhance the prescribing decision process, additional features can be included on screens such as FIG. 7, for example drug pricing information, employing actual wholesale or retail pricing, or comparative pricing or on another manner of drug pricing or grouping, such as a comparative scale or price rating system, or relative pricing based on actual prescription benefit management company contracts. Such pricing information can greatly influence M.D. decision-making, improving formulary compliance and reducing overall drug costs, without restricting a physician's choices.
>
> A powerful optional feature of the invention is shown in exemplary fashion by the drug evaluation screen depicted in FIG. 11. After a physician selects a drug block 121 from one of the screens of FIGS. 7 to 10, the system can optionally scan a drug preference database of preferred drug treatments block 71 and the selected patient's history record for an evaluation of the merits of the selected drug in treating the condition in general and for this selected patient. The drug preference database may be remote and may be maintained, for example, by a managed care organization, HMO, or prescription benefits management company. As the FIG. 11 example shows (which example employs different condition and drug selections from those used in FIGS. 6 and 7) one possible result of the database scan may be an on-screen report with an alert message, in header 126 advising the physician that the selected drug is "Not a first line drug" for treating the selected condition. As a helpful suggestion to the physician the system can also offer alternative drugs, from listings in the drug preference database, as being more meritorious for the treatment of the condition in question (pursuant to the maintaining benefit company's standards or, preferably, to objective literature reports).
>
> To this end, the drug selection evaluation block 169 screen of FIG. 11 comprises an explanatory box 128 elucidating header 126; an alternative drug selection menu 130; and at the bottom of the screen, three action buttons; for example, Tx Guidelines 132 to access treatment information about the alternative drug highlighted in menu 130; a confirm button 134 to post the physician's original drug selection, in this case "Cefixime"

> and to return to prescription creation screen 39; and a cancel button 136 which returns the user to the drug-selection of FIG. 7.
>
> The treatment information available via Tx Guidelines button 132 may include a literature reference supporting the system's finding that Cefixime is not a preferred first line agent for treatment of the selected condition, otitis media. Optionally there may be a selection on a drop-down menu from the Tx Guidelines button 132 enabling a physician, without further effort to have a copy of such a study sent to them. In a further optional embodiment, Tx Guidelines button 132 can provide the user with an access point to full disclosure and prescribing information on the drug. Available treatment guidelines information can include details of the particular conditions for which a system suggested alternative drug has been found effective, adverse conditions, preferred dosages and administration routes, literature sources and so on. This aspect of the inventive system provides a simple, nonintrusive technique for bringing new drug information to physicians at a critical moment of need, when creating a prescription.

As best understood by applicant, the system described by Mayaud provides a drug preference database which presents to a physician a preferred drug or drugs based on patient disease information and certain types of pricing information. As discussed above, there does not appear to be any statistical risk or risk analysis, nor any joint optimization. Note, for example, that the drugs presented in Figs. 7 and 11 are merely in alphabetical order. Mayaud provides no teaching which would enable a person of ordinary skill in the art to practice the technology claimed by applicant to optimize these lists further based on the specified parameters. While Mayaud apparently proposes a system for improving drug prescription management, e.g., Col. 4, lines 20-34, it fails to particularly teach the present claim elements, which is the focus of the Board's adjudication.

It is noted, e.g., with respect to claims 30 and 45, that a dependent claim adopts the limitations of the parent claim, and therefore the interaction of the dependent claim and the parent claim is relevant to a discussion of the patentability thereof.

Likewise, the same object or step cannot correspond to different claim elements. Thus, the "statistical risk" of claim 29 cannot be the same as the "risk tolerance" of claim 31 (see also claim 62); yet, the Examiner alleges that the allergy information satisfies both. The use of tortured phraseology, such as "allergy … indicating *intolerance* toward the allergen" does not remedy the fact that there is no discussion of either statistical risks or risk tolerance in Mayaud.

With respect to claims 33 and 48, it is noted that the "cost optimization" alleged to be taught by Mayaud is nowhere described in the reference. It appears that any such "cost optimization" is performed during data entry and database preparation, and represents a static

determination of "value" which is not thereafter subject to a joint optimization as required by the claims.

Claim 36 provides that the "presented set of records [is further optimized] based on the determined user preference". There appears to be no user preference consideration in an optimization taught and enabled by Mayaud.

With respect to claim 49, there appears no basis in Mayaud to presume that the *order* of the drugs in Fig. 11 is anything other than alphabetical (Amoxicillin, Trimethoprim/Sulfa), and there is no express or implicit teaching that the output is a sorted list of the set of records having an *order* dependent on the determined economic parameters and the determined statistical risk.

The rejection of claim 50 remains indistinct, due to tautology.

Examiner states that Col. 19, line 30 anticipates claim 62, which provides "The method according to claim 59, further comprising the steps of providing a plurality of relevance profiles, and selecting a relevance profile to define a risk tolerance." Col. 19, lines 17-34, reads as follows:

> Patient features bar 40 comprises a Select Patient button 46, a selected patient indicator 48, in this case Mary Harrington, a patient Problems button 50 and a patient Allergies button 52. Beneath Problems button 50 are displayed Mary Harrington's currently active problems 51 or conditions, shown here as pharyngitis and bronchitis. Beneath Allergies button 52 are displayed Mary Harrington's known allergies. Pressing or otherwise activating Problems button 50 or Allergies button 52 access the remote database for the patient's history and, opens a window or screen listing problems or allergies from which a physician, or other professional user, can select new problems or allergies to add to Mary Harrington's record, or delete ones that are no longer active. **Optionally, system-provided problem or allergy libraries may be organized into multiple lists with button 50 or 52, respectively, opening a list selection box as a preliminary to displaying a selected problem or allergy list.**

There is not believed to be any disclosure that a selection of one of a plurality of "relevance profiles" (if met at all by these "problem" or "allergy" libraries), are selected to define a "risk tolerance". Thus, the Examiner has apparently trivialized express claim language in order to shoehorn disparate disclosure to support an anticipation rejection.

Claim 64 further comprises the steps of providing a client terminal having an interface for the user, providing a server for receiving information from the user and optimizing the presented records, and communicating between the client terminal and server over a computer network. While, in general, client-server computing systems are known, and indeed Mayaud discloses

clients 201 and a server 206, the present claim describes that the optimization is performed at the server, thus distinguishing Mayaud which provides not such teaching.

It is therefore believed that the rejections of the Examiner should be reversed.

Respectfully submitted,

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